IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMICUS THERAPEUTICS US, LLC and AMICUS THERAPEUTICS, INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICALS, INC., Defendants.	C.A. No. 22-1461-CJB ANDA CASE (consolidated)

THIRD AMENDED CONSOLIDATED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Amicus Therapeutics US, LLC ("ATUS") and Amicus Therapeutics, Inc. ("AT") (collectively "Amicus" or "Plaintiffs"), by way of Complaint against Defendants Aurobindo Pharma Ltd. ("Aurobindo Pharma Ltd."), and Aurobindo Pharma USA, Inc. ("Aurobindo Pharma USA") (collectively "Aurobindo" or "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 10,792,279 (the "'279 Patent"), 10,806,727 (the "'727 Patent"), 10,849,889 (the "'889 Patent"), 10,849,890 (the "'890 Patent"), 10,874,655 (the "'655 Patent"), 11,278,536 (the "'536 Patent"), 11,278,537 (the "'537 Patent"), 11,278,538 (the "'538 Patent"), 11,278,539 (the "'539 Patent"), 11,278,540 (the "'540 Patent"), 11,357,761 (the "'761 Patent"), 11,357,762 (the "'762 Patent"), 11,357,763 (the "'763 Patent"), 11,389,436 (the "'436 Patent"), 11,389,437 (the "'437 Patent"), 11,458,128 (the "'128 Patent"), 11,304,940 (the "'940 Patent"), 11,357,764 (the "'764 Patent"), 11,357,765 (the "'765 Patent"), 11,376,244 (the "'244 Patent"), 11,426,396 (the "'396 Patent"), 10,874,657 (the

"'657 Patent"), 11,357,784 (the "'784 Patent"), 11,612,593 (the "'593 Patent"), 11,612,594 (the "'594 Patent"), 11,622,962 (the "'962 Patent"), 11,633,387 (the "'387 Patent"), 11,633,388 (the "'388 Patent"), 11,642,334 (the "'334 Patent"), 11,786,516 (the "'516 Patent"), 11,813,255 (the "'255 Patent"), and 11,903,938 (the "'938 Patent") (collectively, "Patents-in-Suit"), arising under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action arises out of Aurobindo's submission of Abbreviated New Drug Application ("ANDA") No. 217786 under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market a generic version of GALAFOLD migalastat 123 mg free base capsules before the expiration of the Patents-in-Suit.

THE PARTIES

2. Amicus Therapeutics US, LLC (*i.e.*, ATUS) is a limited liability company organized and existing under the laws of the state of Delaware with its corporate headquarters at 3675 Market Street, Philadelphia, PA 19104.

3. Amicus Therapeutics, Inc. (*i.e.*, AT) is a corporation organized and existing under the laws of the state of Delaware with its corporate headquarters at 3675 Market Street, Philadelphia, PA 19104.

4. Amicus is a global, patient-dedicated biotechnology company focused on discovering, developing and delivering novel and high-quality medicines for people living with rare diseases. The cornerstone of Amicus's portfolio is GALAFOLD, the first approved oral precision medicine for people living with Fabry disease who have amenable genetic variants. Fabry disease is a genetic disorder known as a lysosomal storage disorder. Fabry disease is caused by a mutation or variant to the GLA gene, which encodes the enzyme α-galactosidase A (α-Gal

A). The variant causes the substrate globotriaosylceramide (GL-3) to accumulate in various tissues and organs.

5. Amicus sells GALAFOLD migalastat 123 mg free base capsules throughout the United States, including in this judicial district.

6. By eight separate letters respectively dated (i) October 6, 2022 ("Aurobindo's October 2022 Notice Letter"), and received by Amicus on October 7, 2022, (ii) November 11, 2022 ("Aurobindo's November 2022 Notice Letter"), and received by Amicus on November 14, 2022, (iii) May 9, 2023 ("Aurobindo's May 2023 Notice Letter"), and received by Amicus on May 10, 2023, (iv) June 16, 2023 ("Aurobindo's June 2023 Notice Letter"), and received by Amicus on June 19, 2023, (v) July 27, 2023 ("Aurobindo's July 2023 Notice Letter"), and received by Amicus on July 28, 2023, (vi) December 13, 2023 ("Aurobindo's December 2023 Notice Letter"), and received by Amicus on December 14, 2023, (vii) February 15, 2024 ("Aurobindo's February 2024 Notice Letter"), and received by Amicus on February 16, 2024, and (viii) May 3, 2024 ("Aurobindo's May 2024 Notice Letter"), and received by Amicus on May 6, 2024 (collectively, "Aurobindo's Notice Letters"), Aurobindo notified Amicus that Aurobindo Pharma Ltd. had submitted an ANDA to the United States FDA ("Aurobindo's ANDA") for "migalastat hydrochloride capsules, EQ 123 mg base," a drug product that is a generic version of GALAFOLD ("Aurobindo's ANDA Product"). Upon information and belief, the purpose of Aurobindo's submission of Aurobindo's ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product prior to the expiration of the Patents-in-Suit.

7. In Aurobindo's October 2022 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to Section 505(j)(2)(B)(iv)(II) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(iv)(II) ("¶ IV") and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent Nos. 10,076,514; 10,251,873; 10,471,053; 10,792,278; 10,792,279; 10,799,491; 10,806,727; 10,849,889; 10,849,890; 10,857,141; 10,857,142; 10,874,655; 10,874,656; 10,874,657; 11,234,972; 11,278,536; 11,278,537; 11,278,538; 11,278,539; 11,278,540; 11,304,940; 11,357,762; 11,357,763; 11,357,764; 11,357,765; 11,357,784; 11,376,244; 11,389,436; and 11,389,437 (collectively, the "October 2022 Patents"), which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluation ("Orange Book").

8. In Aurobindo's November 2022 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent Nos. 11,357,761, 11,426,396, and 11,458,128 (collectively, the "November 2022 Patents"), which are listed in the Orange Book.

9. In Aurobindo's May 2023 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent Nos. 11,612,593; 11,612,594; and 11,622,962 (collectively, the "May 2023 Patents"), which are listed in the Orange Book.

10. In Aurobindo's June 2023 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent Nos. 11,633,387; 11,633,388; and 11,642,334 (collectively, the "June 2023 Patents"), which are listed in the Orange Book.

11. In Aurobindo's July 2023 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent No. 11,666,564 (the "July 2023 Patent"), which is listed in the Orange Book.

12. In Aurobindo's December 2023 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent No. 11,786,516 (the "December 2023 Patent"), which is listed in the Orange Book.

13. In Aurobindo's February 2024 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent Nos. 11,813,255; 11,826,360; and 11,833,164 (collectively, the "February 2024 Patents"), which are listed in the Orange Book.

14. In Aurobindo's May 2024 Notice Letter, Aurobindo notified Amicus that, as part of Aurobindo's ANDA, Aurobindo had filed a certification pursuant to ¶ IV and 21 C.F.R. § 314.95(c)(7), with respect to U.S. Patent Nos. 11,903,938 (the "May 2024 Patent"; together with the October 2022 Patents, November 2022 Patents, May 2023 Patents, June 2023 Patents, July 2023 Patent, December 2023 Patent, and February 2024 Patents, the "Notice Letter Patents"), which is listed in the Orange Book.

15. Aurobindo's Notice Letters assert that the Notice Letter Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product (the "¶ IV Certifications"). Aurobindo's Notice Letters purport to include detailed statements of the factual

and legal bases for Aurobindo's ¶ IV Certifications. Aurobindo's Notice Letters defined Aurobindo as Aurobindo Pharma Ltd.

16. Aurobindo Pharma Ltd. is a company organized under the laws of India having a principal place of business at Maitrivihar, Plot No. 2, Ameerpet, Hyderabad, Telangana 500038, India and Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Hyderabad, Telangana 500032, India.

17. Aurobindo Pharma USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520.

18. Aurobindo Pharma Ltd. is a non-governmental, publicly held corporation and has no parent company. No publicly held company owns 10% or more of the stock of Aurobindo Pharma Ltd.

19. Aurobindo Pharma USA is a wholly-owned subsidiary of Aurobindo Pharma Ltd.

20. Aurobindo Pharma USA has acted as Aurobindo Pharma Ltd.'s agent with respect to Aurobindo's ANDA No. 217786.

21. Upon information and belief, Aurobindo Pharma USA has acted at the direction of, and for the benefit of, Aurobindo Pharma Ltd. regarding Aurobindo's ANDA No. 217786.

22. Aurobindo Pharma Ltd. submitted Drug Master File ("DMF") No. 36827 for migalastat hydrochloride to the FDA on February 25, 2022.

23. Upon information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA are generic pharmaceutical companies that, in coordination with each other and at the direction of Aurobindo Pharma Ltd., are in the business of making and selling generic pharmaceutical products, which they distribute throughout the United States including in this judicial district.

JURISDICTION AND VENUE

24. This is an action for patent infringement arising under 35 U.S.C. § 271. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

25. The Court also has jurisdiction over this action pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and justiciable controversy exists between Amicus and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the parties' adverse legal interests with respect to the Patents-in-Suit.

26. Upon information and belief, Defendants hold themselves out as a unitary entity and operate as a single integrated business directed and/or controlled by Aurobindo Pharma Ltd. with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

27. Upon information and belief, Defendants have and will continue to coordinate, collaborate, and act in concert to prepare, submit, and maintain Aurobindo's ANDA No. 217786 pursuant to Section 505(j) of the FDCA, 21 U.S.C. § 355(j). Defendants are therefore submitters of an ANDA within the jurisdiction of this Court.

28. This Court has personal jurisdiction over Aurobindo Pharma USA because, upon information and belief, its affiliations with and business activities within the State of Delaware and this judicial district, including by virtue of its incorporation in Delaware, are so systematic and continuous as to render Aurobindo Pharma USA essentially at home in this judicial district.

29. This Court has personal jurisdiction over foreign Defendant Aurobindo Pharma Ltd. because, upon information and belief, Aurobindo Pharma Ltd. controls the actions of its agent and United States subsidiary Aurobindo Pharma USA, a Delaware corporation. Therefore, upon

information and belief, the activities of Aurobindo Pharma USA in this jurisdiction are attributable to Aurobindo Pharma Ltd.

30. The Court also has personal jurisdiction over foreign Defendant Aurobindo Pharma Ltd. pursuant to Fed. R. Civ. P. 4(k)(2). This action arises under federal law, out of Aurobindo's submission of an ANDA filing. To the extent Aurobindo Pharma Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, exercising jurisdiction over Aurobindo Pharma Ltd. is consistent with the Constitution and laws of the United States as Aurobindo Pharma Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation, submission, and maintenance of Aurobindo's ANDA, participating in the preparation and submission of DMF No. 36827 to the FDA, and/or directly or indirectly developing, manufacturing, marketing, and selling Aurobindo's ANDA Product throughout the United States, including in this judicial district, such that this Court's exercise of personal jurisdiction over Aurobindo Pharma Ltd. satisfies due process.

31. This Court also has personal jurisdiction over Defendants because, upon information and belief, each has frequently availed itself of the legal protections of the State of Delaware by, among other things, selecting the State of Delaware as the place of incorporation for itself and/or its subsidiaries and asserting claims and counterclaims in lawsuits filed in the United States District Court for the District of Delaware, including at least *Gilead Sciences, Inc. v. Aurobindo Pharma Ltd. et al*, No. 1:21-cv-01735, at Dkt. 9 (D. Del. Feb. 14, 2022) and *Azurity Pharmaceuticals, Inc. v. Aurobindo Pharma Ltd. et al*, No. 1:21-cv-01707, at Dkt. 12 (D. Del. Jan. 7, 2022).

32. This Court also has personal jurisdiction over each Defendant because, upon information and belief, each is a submitter of Aurobindo's ANDA. This Court also has personal

jurisdiction over each Defendant because, upon information and belief, each has committed or aided, abetted, contributed to, or participated in tortious acts of patent infringement in submitting Aurobindo's ANDA that has led to foreseeable harm and injury to Amicus, which manufactures GALAFOLD for sale and use throughout the United States, including within this judicial district. Upon information and belief, each Defendant will imminently commit, or aid, abet, contribute to, or participate in tortious acts of patent infringement by directly or indirectly developing, manufacturing, marketing, and selling Aurobindo's ANDA Product throughout the United States and in this judicial district, which will lead to foreseeable harm and injury to Amicus.

33. Upon information and belief, Defendants have been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 217786 for the United States market. Aurobindo's ANDA No. 217786 relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Aurobindo's intent to market and sell Aurobindo's ANDA Product throughout the United States, including in this judicial district.

34. Aurobindo has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of Aurobindo's ANDA Product—which, upon information and belief, will be purposefully directed at this judicial district and elsewhere throughout the United States. Upon information and belief, Defendants will act in concert to market, distribute, and sell Aurobindo's ANDA Product in this judicial district, among other places, once Aurobindo receives the requested FDA approval to market Aurobindo's ANDA Product.

35. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, each Defendant is subject to personal jurisdiction in this judicial district.

36. Venue is proper for Aurobindo Pharma USA in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Aurobindo Pharma USA is incorporated and therefore resides in the state of Delaware and has committed acts of infringement giving rise to the claims against it in this judicial district. Venue is also proper for Aurobindo Pharma USA in this judicial district because Aurobindo Pharma USA is a submitter of Aurobindo's ANDA.

37. Venue is proper for Aurobindo Pharma Ltd. in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) and/or Fed. R. Civ. P. 4(k)(2) because Aurobindo Pharma Ltd. is incorporated in India and may be sued in any judicial district in the United States. Venue is also proper for Aurobindo Pharma Ltd. in this judicial district because Aurobindo Pharma Ltd. is a submitter of Aurobindo's ANDA.

FACTUAL BACKGROUND

The NDA

38. ATUS is the holder of New Drug Application ("NDA") No. 208623 for GALAFOLD capsules comprising 123 mg free base migalastat ("GALAFOLD Capsules").

39. GALAFOLD is an oral medication administered every other day approved for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable α-galactosidase A (GLA) gene variant. Migalastat, which is an iminosugar, is the active ingredient in GALAFOLD Capsules.

40. The FDA approved NDA No. 208623 on August 10, 2018. GALAFOLD enjoys New Chemical Entity ("NCE") exclusivity until August 10, 2023.

41. GALAFOLD is designated as an orphan drug under the Orphan Drug Act, 21 U.S.C. § 360aa *et seq.* and enjoys Orphan Drug Exclusivity ("ODE") until August 10, 2025.

Amicus markets capsules comprising 123 mg free base migalastat in the United States under the trademark GALAFOLD.

42. Aurobindo advertises that its vision is to "become a consistent top 10 generic pharmaceutical supplier." https://www.aurobindousa.com/company/our-story/mission-values/ (last accessed June 13, 2024).

43. In April 2020, Defendant Aurobindo Pharma USA submitted a request pursuant to 21 U.S.C. § 355-2 (the "CREATES Act") to ATUS seeking to purchase GALAFOLD for testing purportedly deemed necessary by Aurobindo to support Aurobindo's ANDA No. 217786. On March 28, 2022, Aurobindo sent a request to ATUS seeking to purchase an additional seven packs of GALAFOLD to purportedly complete testing required for approval of a generic version of GALAFOLD (*i.e.*, Aurobindo's ANDA Product) pursuant to Aurobindo's ANDA No. 217786.

44. Upon information and belief, Aurobindo intends to develop a generic version of GALAFOLD.

The Patents-in-Suit

45. The United States Patent and Trademark Office (the "PTO") duly and legally issued the '279 Patent on October 6, 2020, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '279 Patent is attached as Exhibit A.

46. AT is the owner of all right, title, and interest in the '279 Patent by assignment recorded with the PTO on August 5, 2022.

47. The '279 Patent currently expires on May 30, 2038.

48. The '279 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

49. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '279 Patent.

50. The PTO duly and legally issued the '727 Patent on October 20, 2020, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '727 Patent is attached as Exhibit B.

51. AT is the owner of all right, title, and interest in the '727 Patent by assignment recorded with the PTO on August 5, 2022.

52. The '727 Patent currently expires on May 30, 2038.

53. The '727 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

54. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '727 Patent.

55. The PTO duly and legally issued the '889 Patent on December 1, 2020, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '889 Patent is attached as Exhibit C.

56. AT is the owner of all right, title, and interest in the '889 Patent by assignment recorded with the PTO on August 5, 2022.

57. The '889 Patent currently expires on May 30, 2038.

58. The '889 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

59. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '889 Patent.

60. The PTO duly and legally issued the ’890 Patent on December 1, 2020, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’890 Patent is attached as Exhibit D.

61. AT is the owner of all right, title, and interest in the ’890 Patent by assignment recorded with the PTO on August 5, 2022.

62. The ’890 Patent currently expires on May 30, 2038.

63. The ’890 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

64. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’890 Patent.

65. The PTO duly and legally issued the ’655 Patent on December 29, 2020, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’655 Patent is attached as Exhibit E.

66. AT is the owner of all right, title, and interest in the ’655 Patent by assignment recorded with the PTO on August 5, 2022.

67. The ’655 Patent currently expires on May 30, 2038.

68. The ’655 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

69. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’655 Patent.

70. The PTO duly and legally issued the ’536 Patent on March 22, 2022, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’536 Patent is attached as Exhibit F.

71. AT is the owner of all right, title, and interest in the ’536 Patent by assignment recorded with the PTO on August 5, 2022.

72. The ’536 Patent currently expires on May 30, 2038.

73. The ’536 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

74. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’536 Patent.

75. The PTO duly and legally issued the ’537 Patent on March 22, 2022, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’537 Patent is attached as Exhibit G.

76. AT is the owner of all right, title, and interest in the ’537 Patent by assignment recorded with the PTO on August 5, 2022.

77. The ’537 Patent currently expires on May 30, 2038.

78. The ’537 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

79. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’537 Patent.

80. The PTO duly and legally issued the ’538 Patent on March 22, 2022, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’538 Patent is attached as Exhibit H.

81. AT is the owner of all right, title, and interest in the ’538 Patent by assignment recorded with the PTO on August 5, 2022.

82. The ’538 Patent currently expires on May 30, 2038.

83. The ’538 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

84. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’538 Patent.

85. The PTO duly and legally issued the ’539 Patent on March 22, 2022, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’539 Patent is attached as Exhibit I.

86. AT is the owner of all right, title, and interest in the ’539 Patent by assignment recorded with the PTO on August 5, 2022.

87. The ’539 Patent currently expires on May 30, 2038.

88. The ’539 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

89. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’539 Patent.

90. The PTO duly and legally issued the ’540 Patent on March 22, 2022, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’540 Patent is attached as Exhibit J.

91. AT is the owner of all right, title, and interest in the ’540 Patent by assignment recorded with the PTO on August 5, 2022.

92. The ’540 Patent currently expires on May 30, 2038.

93. The ’540 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

94. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '540 Patent.

95. The PTO duly and legally issued the '761 Patent on June 14, 2022, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '761 Patent is attached as Exhibit K.

96. AT is the owner of all right, title, and interest in the '761 Patent by assignment recorded with the PTO on August 5, 2022.

97. The '761 Patent currently expires on May 30, 2038.

98. The '761 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

99. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '761 Patent.

100. The PTO duly and legally issued the '762 Patent on June 14, 2022, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '762 Patent is attached as Exhibit L.

101. AT is the owner of all right, title, and interest in the '762 Patent by assignment recorded with the PTO on August 5, 2022.

102. The '762 Patent currently expires on May 30, 2038.

103. The '762 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

104. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '762 Patent.

105. The PTO duly and legally issued the '763 Patent on June 14, 2022, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '763 Patent is attached as Exhibit M.

106. AT is the owner of all right, title, and interest in the '763 Patent by assignment recorded with the PTO on August 5, 2022.

107. The '763 Patent currently expires on May 30, 2038.

108. The '763 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

109. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '763 Patent.

110. The PTO duly and legally issued the '436 Patent on July 19, 2022, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '436 Patent is attached as Exhibit N.

111. AT is the owner of all right, title, and interest in the '436 Patent by assignment recorded with the PTO on August 5, 2022.

112. The '436 Patent currently expires on May 30, 2038.

113. The '436 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

114. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '436 Patent.

115. The PTO duly and legally issued the '437 Patent on July 19, 2022, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '437 Patent is attached as Exhibit O.

116. AT is the owner of all right, title, and interest in the '437 Patent by assignment recorded with the PTO on August 5, 2022.

117. The '437 Patent currently expires on May 30, 2038.

118. The '437 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

119. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '437 Patent.

120. The PTO duly and legally issued the '128 Patent on October 4, 2022, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '128 Patent is attached as Exhibit P.

121. AT is the owner of all right, title, and interest in the '128 Patent by assignment recorded with the PTO on August 5, 2022.

122. The '128 Patent currently expires on May 30, 2038.

123. The '128 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

124. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '128 Patent.

125. The PTO duly and legally issued the '940 Patent on April 19, 2022, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '940 Patent is attached as Exhibit Q.

126. AT is the owner of all right, title, and interest in the '940 Patent by assignment recorded with the PTO on August 5, 2022.

127. The '940 Patent currently expires on May 30, 2038.

128. The ’940 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

129. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’940 Patent.

130. The PTO duly and legally issued the ’764 Patent on June 14, 2022, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’764 Patent is attached as Exhibit R.

131. AT is the owner of all right, title, and interest in the ’764 Patent by assignment recorded with the PTO on August 5, 2022.

132. The ’764 Patent currently expires on May 30, 2038.

133. The ’764 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

134. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’764 Patent.

135. The PTO duly and legally issued the ’765 Patent on June 14, 2022, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’765 Patent is attached as Exhibit S.

136. AT is the owner of all right, title, and interest in the ’765 Patent by assignment recorded with the PTO on August 5, 2022.

137. The ’765 Patent currently expires on May 30, 2038.

138. The ’765 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

139. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '765 Patent.

140. The PTO duly and legally issued the '244 Patent on July 5, 2022, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '244 Patent is attached as Exhibit T.

141. AT is the owner of all right, title, and interest in the '244 Patent by assignment recorded with the PTO on August 5, 2022.

142. The '244 Patent currently expires on May 30, 2038.

143. The '244 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

144. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '244 Patent.

145. The PTO duly and legally issued the '396 Patent on August 30, 2022, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '396 Patent is attached as Exhibit U.

146. AT is the owner of all right, title, and interest in the '396 Patent by assignment recorded with the PTO on August 5, 2022.

147. The '396 Patent currently expires on May 30, 2038.

148. The '396 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

149. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '396 Patent.

150. The PTO duly and legally issued the '657 Patent on December 29, 2020, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '657 Patent is attached as Exhibit V.

151. AT is the owner of all right, title, and interest in the '657 Patent by assignment recorded with the PTO on August 5, 2022.

152. The '657 Patent currently expires on May 30, 2038.

153. The '657 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

154. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '657 Patent.

155. The PTO duly and legally issued the '784 Patent on June 14, 2022, titled "Use of Migalastat for Treating Fabry Disease in Pregnant Patients." A true and correct copy of the '784 Patent is attached as Exhibit W.

156. AT is the owner of all right, title, and interest in the '784 Patent by assignment recorded with the PTO on February 17, 2022.

157. The '784 Patent currently expires on February 6, 2039.

158. The '784 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

159. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '784 Patent.

160. The PTO duly and legally issued the '593 Patent on March 28, 2023, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '593 Patent is attached as Exhibit X.

161. AT is the owner of all right, title, and interest in the ’593 Patent by assignment recorded with the PTO on August 5, 2022.

162. The ’593 Patent currently expires on May 30, 2038.

163. The ’593 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

164. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’593 Patent.

165. The PTO duly and legally issued the ’594 Patent on March 28, 2023, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’594 Patent is attached as Exhibit Y.

166. AT is the owner of all right, title, and interest in the ’594 Patent by assignment recorded with the PTO on August 5, 2022.

167. The ’594 Patent currently expires on May 30, 2038.

168. The ’594 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

169. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’594 Patent.

170. The PTO duly and legally issued the ’962 Patent on April 11, 2023, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’962 Patent is attached as Exhibit Z.

171. AT is the owner of all right, title, and interest in the ’962 Patent by assignment recorded with the PTO on August 5, 2022.

172. The ’962 Patent currently expires on March 17, 2039.

173. The ’962 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

174. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’962 Patent.

175. The PTO duly and legally issued the ’387 Patent on April 25, 2023, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’387 Patent is attached as Exhibit AA.

176. AT is the owner of all right, title, and interest in the ’387 Patent by assignment recorded with the PTO on August 5, 2022.

177. The ’387 Patent currently expires on May 30, 2038.

178. The ’387 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

179. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’387 Patent.

180. The PTO duly and legally issued the ’388 Patent on April 25, 2023, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’388 Patent is attached as Exhibit BB.

181. AT is the owner of all right, title, and interest in the ’388 Patent by assignment recorded with the PTO on August 5, 2022.

182. The ’388 Patent currently expires on March 25, 2039.

183. The ’388 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

184. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’388 Patent.

185. The PTO duly and legally issued the ’334 Patent on May 9, 2023, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’334 Patent is attached as Exhibit CC.

186. AT is the owner of all right, title, and interest in the ’334 Patent by assignment recorded with the PTO on August 5, 2022.

187. The ’334 Patent currently expires on February 20, 2039.

188. The ’334 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

189. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’334 Patent.

190. The United States Patent and Trademark Office (the “PTO”) duly and legally issued the ’516 Patent on October 17, 2023, titled “Methods of Treating Fabry Patients Having Renal Impairment.” A true and correct copy of the ’516 Patent is attached as Exhibit DD.

191. AT is the owner of all right, title, and interest in the ’516 Patent by assignment recorded with the PTO on August 5, 2022.

192. The ’516 Patent currently expires on May 30, 2038.

193. The ’516 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

194. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the ’516 Patent.

195. The United States Patent and Trademark Office (the "PTO") duly and legally issued the '255 Patent on November 14, 2023, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '255 Patent is attached as Exhibit EE.

196. AT is the owner of all right, title, and interest in the '255 Patent by assignment recorded with the PTO on August 5, 2022.

197. The '255 Patent currently expires on May 30, 2038.

198. The '255 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

199. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '255 Patent.

200. The United States Patent and Trademark Office (the "PTO") duly and legally issued the '938 Patent on February 20, 2024, titled "Methods of Treating Fabry Patients Having Renal Impairment." A true and correct copy of the '938 Patent is attached as Exhibit FF.

201. AT is the owner of all right, title, and interest in the '938 Patent by assignment recorded with the PTO on August 5, 2022.

202. The '938 Patent currently expires on August 17, 2038.

203. The '938 Patent is listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

204. Administration of GALAFOLD in accordance with the FDA-approved prescribing information practices one or more claims of the '938 Patent.

AUROBINDO'S ANDA

205. Upon information and belief, Aurobindo submitted ANDA No. 217786 with the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use,

offer for sale, sale, and/or importation within or into the United States of 123 mg free base migalastat capsules (defined above as "Aurobindo's ANDA Product"), which are generic versions of Amicus' GALAFOLD Capsules.

206. Aurobindo's Notice Letters purport to include a "Notification of Paragraph IV Certification Regarding [the Notice Letter Patents]" pursuant to § 505(j)(2)(B)(i)-(iv) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7). Together, Aurobindo's Notice Letters state that Aurobindo's ANDA seeks FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the Patents-in-Suit.

207. Aurobindo's Notice Letters state that ANDA No. 217786 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), alleging that the claims of the Patents-in-Suit are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product (defined above as Aurobindo's "¶ IV Certifications").

208. Amicus commenced this action within 45 days of receiving Aurobindo's October 2022 Notice Letter, which triggers a stay of FDA approval of Aurobindo's ANDA No. 217786, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). Amicus filed this Amended Complaint within 45 days of receiving Aurobindo's November 2022 Notice Letter, which triggers a stay of FDA approval of Aurobindo's ANDA No. 217786, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

209. Upon information and belief, Aurobindo will knowingly provide Aurobindo's ANDA Product with a label ("Aurobindo's Label") including instructions for use that substantially copy the instructions in the label for GALAFOLD Capsules.

210. Upon information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product that will be administered to patients according to the instructions for use on Aurobindo's Label.

211. Upon information and belief, Aurobindo's ANDA Product will be administered to patients according to the instructions for use on Aurobindo's Label, which will result in formation of the compositions claimed by the Patents-in-Suit prior to their expiration.

212. Upon information and belief, Aurobindo's ANDA Product will be administered to patients using the methods claimed by the Patents-in-Suit prior to their expiration.

213. Upon information and belief, Aurobindo continues to seek approval of ANDA No. 217786, and upon approval by the FDA, Aurobindo intends to immediately engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product.

214. Upon information and belief, upon approval by the FDA, and upon commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States, Aurobindo's ANDA Product will be administered to patients according to the instructions for use on Aurobindo's Label, which will practice the compositions and methods claimed by the Patents-in-Suit prior to their expiration.

215. Upon information and belief, the compositions and methods covered by the claims of the Patents-in-Suit are an essential component of administering Aurobindo's ANDA Product to patients.

216. Upon information and belief, Aurobindo will direct or control the treatment of patients using Aurobindo's ANDA Product if the FDA approves ANDA No. 217786.

217. Upon information and belief, the treatment of patients using Aurobindo's ANDA Product will occur at Aurobindo's active behest and with its intent, knowledge, and encouragement.

218. Upon information and belief, Aurobindo will actively encourage, aid, and abet the treatment of patients using Aurobindo's ANDA Product with knowledge that such treatment is in contravention of Amicus' rights under the Patents-in-Suit.

219. Upon information and belief, Aurobindo knows the instructions for use in Aurobindo's Label will induce and/or contribute to others using Aurobindo's ANDA Product in the manner set forth in the instructions.

220. Upon information and belief, physicians, health care providers, and/or patients will directly infringe one or more claims of the Patents-in-Suit by using Aurobindo's ANDA Product in accordance with the instructions for use provided in Aurobindo's Label.

221. Upon information and belief, Aurobindo specifically intends that physicians, health care providers, and/or patients will use Aurobindo's ANDA Product in accordance with the instructions for use provided in Aurobindo's Label to directly infringe one or more claims of the Patents-in-Suit.

222. Upon information and belief, Aurobindo knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using Aurobindo's ANDA Product in a manner that directly infringes at least one claim of the Patents-in-Suit.

223. Upon information and belief, Aurobindo knows or should know that Aurobindo's ANDA Product will be especially made or especially adapted for use in infringement of at least

one claim of the Patents-in-Suit, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

224. Upon information and belief, Aurobindo will actively induce and/or contribute to infringement of the Patents-in-Suit.

COUNT I

(INFRINGEMENT OF THE '279 PATENT)

225. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

226. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '279 Patent.

227. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '279 Patent are invalid, unenforceable, and/or will not be infringed.

228. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

229. Aurobindo has actual knowledge of the '279 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

230. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '279 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786

seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '279 Patent.

231. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '279 Patent.

232. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

233. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '279 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '279 Patent.

234. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

235. Aurobindo has knowledge of the '279 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '279 Patent, either literally or under the doctrine of equivalents.

236. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product

according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '279 Patent.

237. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

238. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '279 Patent unless enjoined by the Court.

239. Amicus does not have any adequate remedy at law.

COUNT II

(INFRINGEMENT OF THE '727 PATENT)

240. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

241. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '727 Patent.

242. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '727 Patent are invalid, unenforceable, and/or will not be infringed.

243. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

244. Aurobindo has actual knowledge of the '727 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

245. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '727 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '727 Patent.

246. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '727 Patent.

247. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

248. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '727 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '727 Patent.

249. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

250. Aurobindo has knowledge of the '727 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '727 Patent, either literally or under the doctrine of equivalents.

251. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '727 Patent.

252. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

253. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '727 Patent unless enjoined by the Court.

254. Amicus does not have any adequate remedy at law.

COUNT III

(INFRINGEMENT OF PATENT '889)

255. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

256. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '889 Patent.

257. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '889 Patent are invalid, unenforceable, and/or will not be infringed.

258. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of

administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

259. Aurobindo has actual knowledge of the '889 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

260. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '889 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '889 Patent.

261. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '889 Patent.

262. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

263. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '889 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '889 Patent.

264. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

265. Aurobindo has knowledge of the '889 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '889 Patent, either literally or under the doctrine of equivalents.

266. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '889 Patent.

267. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

268. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '889 Patent unless enjoined by the Court.

269. Amicus does not have any adequate remedy at law.

COUNT IV

(INFRINGEMENT OF THE '890 PATENT)

270. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

271. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '890 Patent.

272. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '890 Patent are invalid, unenforceable, and/or will not be infringed.

273. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

274. Aurobindo has actual knowledge of the '890 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

275. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '890 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '890 Patent.

276. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '890 Patent.

277. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

278. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '890 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '890 Patent.

279. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

280. Aurobindo has knowledge of the '890 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '890 Patent, either literally or under the doctrine of equivalents.

281. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '890 Patent.

282. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

283. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '890 Patent unless enjoined by the Court.

284. Amicus does not have any adequate remedy at law.

COUNT V

(INFRINGEMENT OF THE '655 PATENT)

285. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

286. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '655 Patent.

287. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '655 Patent are invalid, unenforceable, and/or will not be infringed.

288. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

289. Aurobindo has actual knowledge of the '655 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

290. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '655 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '655 Patent.

291. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '655 Patent.

292. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

293. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '655 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or

contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '655 Patent.

294. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

295. Aurobindo has knowledge of the '655 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '655 Patent, either literally or under the doctrine of equivalents.

296. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '655 Patent.

297. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

298. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '655 Patent unless enjoined by the Court.

299. Amicus does not have any adequate remedy at law.

COUNT VI

(INFRINGEMENT OF THE '536 PATENT)

300. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

301. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '536 Patent.

302. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '536 Patent are invalid, unenforceable, and/or will not be infringed.

303. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

304. Aurobindo has actual knowledge of the '536 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

305. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '536 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '536 Patent.

306. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '536 Patent.

307. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

308. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the ’536 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo’s ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the ’536 Patent.

309. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo’s ANDA Product according to the instructions for use in Aurobindo’s Label.

310. Aurobindo has knowledge of the ’536 Patent and, by virtue of Aurobindo’s Label for Aurobindo’s ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the ’536 Patent, either literally or under the doctrine of equivalents.

311. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo’s Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo’s ANDA Product according to the instructions for use in Aurobindo’s Label in a way that directly infringes at least one claim of the ’536 Patent.

312. Aurobindo’s actions relating to Aurobindo’s ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

313. Amicus will be substantially and irreparably harmed by Aurobindo’s infringement of the ’536 Patent unless enjoined by the Court.

314. Amicus does not have any adequate remedy at law.

COUNT VII

(INFRINGEMENT OF THE '537 PATENT)

315. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

316. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '537 Patent.

317. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '537 Patent are invalid, unenforceable, and/or will not be infringed.

318. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

319. Aurobindo has actual knowledge of the '537 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

320. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '537 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '537 Patent.

321. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '537 Patent.

322. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

323. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '537 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '537 Patent.

324. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

325. Aurobindo has knowledge of the '537 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '537 Patent, either literally or under the doctrine of equivalents.

326. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '537 Patent.

327. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

328. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '537 Patent unless enjoined by the Court.

329. Amicus does not have any adequate remedy at law.

COUNT VIII

(INFRINGEMENT OF THE '538 PATENT)

330. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

331. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '538 Patent.

332. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '538 Patent are invalid, unenforceable, and/or will not be infringed.

333. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

334. Aurobindo has actual knowledge of the '538 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

335. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '538 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '538 Patent.

336. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '538 Patent.

337. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

338. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '538 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '538 Patent.

339. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

340. Aurobindo has knowledge of the '538 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '538 Patent, either literally or under the doctrine of equivalents.

341. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '538 Patent.

342. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

343. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '538 Patent unless enjoined by the Court.

344. Amicus does not have any adequate remedy at law.

COUNT IX

(INFRINGEMENT OF THE '539 PATENT)

345. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

346. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '539 Patent.

347. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '539 Patent are invalid, unenforceable, and/or will not be infringed.

348. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

349. Aurobindo has actual knowledge of the '539 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

350. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '539 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786

seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '539 Patent.

351. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '539 Patent.

352. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

353. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '539 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '539 Patent.

354. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

355. Aurobindo has knowledge of the '539 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '539 Patent, either literally or under the doctrine of equivalents.

356. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product

according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '539 Patent.

357. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

358. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '539 Patent unless enjoined by the Court.

359. Amicus does not have any adequate remedy at law.

COUNT X

(INFRINGEMENT OF THE '540 PATENT)

360. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

361. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '540 Patent.

362. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '540 Patent are invalid, unenforceable, and/or will not be infringed.

363. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

364. Aurobindo has actual knowledge of the '540 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

365. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '540 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '540 Patent.

366. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '540 Patent.

367. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

368. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '540 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '540 Patent.

369. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

370. Aurobindo has knowledge of the '540 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '540 Patent, either literally or under the doctrine of equivalents.

371. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '540 Patent.

372. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

373. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '540 Patent unless enjoined by the Court.

374. Amicus does not have any adequate remedy at law.

COUNT XI

(INFRINGEMENT OF THE '761 PATENT)

375. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

376. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules, which includes the '761 Patent.

377. Aurobindo's Notice Letters state that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of certain patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules are invalid, unenforceable, and/or will not be infringed.

378. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

379. Aurobindo has actual and/or constructive notice of the '761 Patent prior to this suit as evidenced by the '761 Patent's listing in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules. Aurobindo's October 2022 Notice Letter did not provide a ¶ IV certification for the '761 Patent under 21 C.F.R. § 314.95(b) and 35 U.S.C. § 355(j)(2)(B)(ii). Aurobindo's November 2022 Notice Letter states that Aurobindo filed with the FDA a ¶ IV Certification for the '761 Patent alleging the claims of the '761 Patent are invalid, unenforceable, and/or will not be infringed. Upon information and belief, Aurobindo's ¶ IV Certification and/or Aurobindo's notice to Amicus of its ¶ IV Certification for the '761 Patent was untimely under 21 U.S.C. § 355(j)(2)(B)(ii)(I) and/or 21 C.F.R. § 314.95(d).

380. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '761 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules, which includes the '761 Patent.

381. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '761 Patent.

382. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

383. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '761 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '761 Patent.

384. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

385. Aurobindo has actual and/or constructive knowledge of the '761 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '761 Patent, either literally or under the doctrine of equivalents.

386. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '761 Patent.

387. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

388. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '761 Patent unless enjoined by the Court.

389. Amicus does not have any adequate remedy at law.

COUNT XII

(INFRINGEMENT OF THE '762 PATENT)

390. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

391. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '762 Patent.

392. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '762 Patent are invalid, unenforceable, and/or will not be infringed.

393. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

394. Aurobindo has actual knowledge of the '762 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

395. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '762 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '762 Patent.

396. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '762 Patent.

397. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

398. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '762 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '762 Patent.

399. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

400. Aurobindo has knowledge of the '762 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '762 Patent, either literally or under the doctrine of equivalents.

401. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '762 Patent.

402. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

403. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '762 Patent unless enjoined by the Court.

404. Amicus does not have any adequate remedy at law.

COUNT XIII

(INFRINGEMENT OF THE '763 PATENT)

405. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

406. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '763 Patent.

407. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '763 Patent are invalid, unenforceable, and/or will not be infringed.

408. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

409. Aurobindo has actual knowledge of the '763 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

410. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '763 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786

seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '763 Patent.

411. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '763 Patent.

412. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

413. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '763 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '763 Patent.

414. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

415. Aurobindo has knowledge of the '763 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '763 Patent, either literally or under the doctrine of equivalents.

416. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product

according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '763 Patent.

417. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

418. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '763 Patent unless enjoined by the Court.

419. Amicus does not have any adequate remedy at law.

COUNT XIV

(INFRINGEMENT OF THE '436 PATENT)

420. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

421. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '436 Patent.

422. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '436 Patent are invalid, unenforceable, and/or will not be infringed.

423. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

424. Aurobindo has actual knowledge of the '436 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

425. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '436 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '436 Patent.

426. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '436 Patent.

427. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

428. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '436 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '436 Patent.

429. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

430. Aurobindo has knowledge of the '436 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '436 Patent, either literally or under the doctrine of equivalents.

431. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '436 Patent.

432. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

433. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '436 Patent unless enjoined by the Court.

434. Amicus does not have any adequate remedy at law.

COUNT XV

(INFRINGEMENT OF THE '437 PATENT)

435. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

436. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '437 Patent.

437. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '437 Patent are invalid, unenforceable, and/or will not be infringed.

438. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of

administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

439. Aurobindo has actual knowledge of the '437 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

440. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '437 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '437 Patent.

441. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '437 Patent.

442. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

443. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '437 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '437 Patent.

444. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

445. Aurobindo has knowledge of the '437 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '437 Patent, either literally or under the doctrine of equivalents.

446. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '437 Patent.

447. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

448. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '437 Patent unless enjoined by the Court.

449. Amicus does not have any adequate remedy at law.

COUNT XVI

(INFRINGEMENT OF THE '128 PATENT)

450. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

451. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules, which includes the '128 Patent.

452. Aurobindo's Notice Letters state that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of

certain patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules are invalid, unenforceable, and/or will not be infringed. Aurobindo's November 2022 Notice Letter states that Aurobindo filed with the FDA a ¶ IV Certification alleging that the claims of the '128 Patent are invalid, unenforceable, and/or will not be infringed.

453. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

454. Aurobindo had actual and/or constructive notice of the '128 Patent prior to this suit as evidenced by the '128 Patent's listing in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules and Aurobindo has actual knowledge of the '128 Patent, as evidenced by Aurobindo's November 2022 Notice Letter.

455. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '128 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '128 Patent.

456. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '128 Patent.

457. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

458. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '128 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '128 Patent.

459. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

460. Aurobindo has actual and/or constructive knowledge of the '128 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '128 Patent, either literally or under the doctrine of equivalents.

461. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '128 Patent.

462. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

463. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '128 Patent unless enjoined by the Court.

464. Amicus does not have any adequate remedy at law.

COUNT XVII

(INFRINGEMENT OF THE '940 PATENT)

465. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

466. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '940 Patent.

467. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '940 Patent are invalid, unenforceable, and/or will not be infringed.

468. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

469. Aurobindo has actual knowledge of the '940 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

470. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '940 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '940 Patent.

471. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '940 Patent.

472. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

473. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '940 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '940 Patent.

474. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

475. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '940 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '940 Patent, either literally or under the doctrine of equivalents.

476. Aurobindo has knowledge of the '940 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '940 Patent, either literally or under the doctrine of equivalents.

477. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '940 Patent.

478. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

479. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '940 Patent unless enjoined by the Court.

480. Amicus does not have any adequate remedy at law.

COUNT XVIII

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '940 PATENT)

481. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

482. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

483. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the '940 Patent such that the Court may entertain Amicus's request for declaratory relief consistent with Article III of the U.S. Constitution.

484. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '940 Patent.

485. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '940 Patent are invalid, unenforceable, and/or will not be infringed.

486. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of

administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

487. Aurobindo has actual knowledge of the ’940 Patent, as evidenced by Aurobindo’s October 2022 Notice Letter.

488. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo’s ANDA Product within or into the United States before the expiration of the ’940 Patent.

489. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo’s ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

490. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the ’940 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the ’940 Patent.

491. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo’s ANDA Product according to the instructions for use in Aurobindo’s Label.

492. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo’s ANDA Product according to the instructions for use in Aurobindo’s Label, such physicians and patients will make and use the compositions claimed in the ’940 Patent, and therefore such physicians and patients will directly infringe at least one claim of the ’940 Patent, either literally or under the doctrine of equivalents.

493. Aurobindo has knowledge of the ’940 Patent and, by virtue of Aurobindo’s Label for Aurobindo’s ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the ’940 Patent, either literally or under the doctrine of equivalents.

494. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo’s Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo’s ANDA Product according to the instructions for use in Aurobindo’s Label in a way that directly infringes at least one claim of the ’940 Patent.

495. Aurobindo’s actions relating to Aurobindo’s ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

496. Aurobindo’s conduct including, but not limited to, Aurobindo’s filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo’s ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and meaningful preparations to infringe the ’940 Patent and that Aurobindo intends to engage in the commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of Aurobindo’s ANDA Product immediately and imminently upon final approval of Aurobindo’s ANDA and prior to the expiration of the ’940 Patent.

497. Aurobindo’s actions indicate that it does not intend to change its course of action to avoid infringing the ’940 Patent.

498. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo’s ANDA Product prior to expiration of the ’940 Patent will constitute infringement of the ’940 Patent under 35 U.S.C. § 271(b).

499. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '940 Patent unless enjoined by the Court.

500. Amicus does not have any adequate remedy at law.

COUNT XIX

(INFRINGEMENT OF THE '764 PATENT)

501. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

502. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '764 Patent.

503. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '764 Patent are invalid, unenforceable, and/or will not be infringed.

504. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

505. Aurobindo has actual knowledge of the '764 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

506. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '764 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '764 Patent.

507. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '764 Patent.

508. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

509. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '764 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '764 Patent.

510. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

511. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '764 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '764 Patent, either literally or under the doctrine of equivalents.

512. Aurobindo has knowledge of the '764 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '764 Patent, either literally or under the doctrine of equivalents.

513. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing

use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '764 Patent.

514. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

515. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '764 Patent unless enjoined by the Court.

516. Amicus does not have any adequate remedy at law.

COUNT XX

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '764 PATENT)

517. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

518. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

519. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the '764 Patent such that the Court may entertain Amicus's request for declaratory relief consistent with Article III of the U.S. Constitution.

520. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '764 Patent.

521. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '764 Patent are invalid, unenforceable, and/or will not be infringed.

522. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

523. Aurobindo has actual knowledge of the '764 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

524. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '764 Patent.

525. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

526. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '764 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '764 Patent.

527. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

528. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '764 Patent,

and therefore such physicians and patients will directly infringe at least one claim of the '764 Patent, either literally or under the doctrine of equivalents.

529. Aurobindo has knowledge of the '764 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '764 Patent, either literally or under the doctrine of equivalents.

530. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '764 Patent.

531. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

532. Aurobindo's conduct including, but not limited to, Aurobindo's filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo's ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and meaningful preparations to infringe the '764 Patent and that Aurobindo intends to engage in the commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of Aurobindo's ANDA Product immediately and imminently upon final approval of Aurobindo's ANDA and prior to the expiration of the '764 Patent.

533. Aurobindo's actions indicate that it does not intend to change its course of action to avoid infringing the '764 Patent.

534. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to expiration of the '764 Patent will constitute infringement of the '764 Patent under 35 U.S.C. § 271(b).

535. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '764 Patent unless enjoined by the Court.

536. Amicus does not have any adequate remedy at law.

COUNT XXI

(INFRINGEMENT OF THE '765 PATENT)

537. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

538. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '765 Patent.

539. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '765 Patent are invalid, unenforceable, and/or will not be infringed.

540. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

541. Aurobindo has actual knowledge of the '765 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

542. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '765 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '765 Patent.

543. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '765 Patent.

544. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

545. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '765 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '765 Patent.

546. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

547. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '765 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '765 Patent, either literally or under the doctrine of equivalents.

548. Aurobindo has knowledge of the '765 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '765 Patent, either literally or under the doctrine of equivalents.

549. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '765 Patent.

550. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

551. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '765 Patent unless enjoined by the Court.

552. Amicus does not have any adequate remedy at law.

COUNT XXII

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '765 PATENT)

553. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

554. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

555. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the '765 Patent such that the Court may entertain Amicus's request for declaratory relief consistent with Article III of the U.S. Constitution.

556. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '765 Patent.

557. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '765 Patent are invalid, unenforceable, and/or will not be infringed.

558. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

559. Aurobindo has actual knowledge of the '765 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

560. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '765 Patent.

561. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

562. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '765 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '765 Patent.

563. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

564. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '765 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '765 Patent, either literally or under the doctrine of equivalents.

565. Aurobindo has knowledge of the '765 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '765 Patent, either literally or under the doctrine of equivalents.

566. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '765 Patent.

567. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

568. Aurobindo's conduct including, but not limited to, Aurobindo's filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo's ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and meaningful preparations to infringe the '765 Patent and that Aurobindo intends to engage in the commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of

Aurobindo's ANDA Product immediately and imminently upon final approval of Aurobindo's ANDA and prior to the expiration of the '765 Patent.

569. Aurobindo's actions indicate that it does not intend to change its course of action to avoid infringing the '765 Patent.

570. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to expiration of the '765 Patent will constitute infringement of the '765 Patent under 35 U.S.C. § 271(b).

571. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '765 Patent unless enjoined by the Court.

572. Amicus does not have any adequate remedy at law.

COUNT XXIII

(INFRINGEMENT OF THE '244 PATENT)

573. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

574. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '244 Patent.

575. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '244 Patent are invalid, unenforceable, and/or will not be infringed.

576. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of

administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

577. Aurobindo has actual knowledge of the '244 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

578. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '244 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '244 Patent.

579. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '244 Patent.

580. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

581. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '244 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '244 Patent.

582. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

583. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's

Label, such physicians and patients will make and use the compositions claimed in the '244 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '244 Patent, either literally or under the doctrine of equivalents.

584. Aurobindo has knowledge of the '244 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '244 Patent, either literally or under the doctrine of equivalents.

585. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '244 Patent.

586. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

587. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '244 Patent unless enjoined by the Court.

588. Amicus does not have any adequate remedy at law.

COUNT XXIV

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '244 PATENT)

589. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

590. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

591. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the '244

Patent such that the Court may entertain Amicus's request for declaratory relief consistent with Article III of the U.S. Constitution.

592. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '244 Patent.

593. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '244 Patent are invalid, unenforceable, and/or will not be infringed.

594. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

595. Aurobindo has actual knowledge of the '244 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

596. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '244 Patent.

597. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

598. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '244 Patent under § 271(b), either literally or under the

doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '244 Patent.

599. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

600. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '244 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '244 Patent, either literally or under the doctrine of equivalents.

601. Aurobindo has knowledge of the '244 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '244 Patent, either literally or under the doctrine of equivalents.

602. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '244 Patent.

603. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

604. Aurobindo's conduct including, but not limited to, Aurobindo's filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo's ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and

meaningful preparations to infringe the ’244 Patent and that Aurobindo intends to engage in the commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of Aurobindo’s ANDA Product immediately and imminently upon final approval of Aurobindo’s ANDA and prior to the expiration of the ’244 Patent.

605. Aurobindo’s actions indicate that it does not intend to change its course of action to avoid infringing the ’244 Patent.

606. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo’s ANDA Product prior to expiration of the ’244 Patent will constitute infringement of the ’244 Patent under 35 U.S.C. § 271(b).

607. Amicus will be substantially and irreparably harmed by Aurobindo’s infringement of the ’244 Patent unless enjoined by the Court.

608. Amicus does not have any adequate remedy at law.

COUNT XXV

(INFRINGEMENT OF THE ’396 PATENT)

609. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

610. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo’s ANDA Product before the expiration of patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules, which includes the ’396 Patent.

611. Aurobindo’s Notice Letters state that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of certain patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD

Capsules are invalid, unenforceable, and/or will not be infringed. Aurobindo's November 2022 Notice Letter states that Aurobindo filed with the FDA a ¶ IV Certification alleging that the claims of the '396 Patent are invalid, unenforceable, and/or will not be infringed.

612. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

613. Aurobindo had actual and/or constructive notice of the '396 Patent prior to this suit as evidenced by the '396 Patent's listing in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules and Aurobindo has actual knowledge of the '396 Patent, as evidenced by Aurobindo's November 2022 Notice Letter.

614. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '396 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '396 Patent.

615. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '396 Patent.

616. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

617. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '396 Patent under § 271(b), either literally or under the

doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '396 Patent.

618. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

619. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '396 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '396 Patent, either literally or under the doctrine of equivalents.

620. Aurobindo has actual and/or constructive knowledge of the '396 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, know or should know that it will induce direct infringement of at least one claim of the '396 Patent, either literally or under the doctrine of equivalents.

621. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '396 Patent.

622. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

623. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '396 Patent unless enjoined by the Court.

624. Amicus does not have any adequate remedy at law.

COUNT XXVI

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '396 PATENT)

625. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

626. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

627. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the '396 Patent such that the Court may entertain Amicus's request for declaratory relief consistent with Article III of the U.S. Constitution.

628. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules, which includes the '396 Patent.

629. Aurobindo's Notice Letters state that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of certain patents listed in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules are invalid, unenforceable, and/or will not be infringed. Aurobindo's November 2022 Notice Letter states that Aurobindo filed with the FDA a ¶ IV Certification alleging that the claims of the '396 Patent are invalid, unenforceable, and/or will not be infringed.

630. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of

administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

631. Aurobindo had actual and/or constructive notice of the '396 Patent prior to this suit as evidenced by the '396 Patent's listing in the Orange Book in connection with NDA No. 208623 for GALAFOLD Capsules.

632. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '396 Patent.

633. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

634. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '396 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '396 Patent.

635. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

636. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '396 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '396 Patent, either literally or under the doctrine of equivalents.

637. Aurobindo has actual and/or constructive knowledge of the '396 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '396 Patent, either literally or under the doctrine of equivalents.

638. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '396 Patent.

639. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

640. Aurobindo's conduct including, but not limited to, Aurobindo's filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo's ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and meaningful preparations to infringe the '396 Patent and that Aurobindo intends to engage in the commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of Aurobindo's ANDA Product immediately and imminently upon final approval of Aurobindo's ANDA and prior to the expiration of the '396 Patent.

641. Aurobindo's actions indicate that it does not intend to change its course of action to avoid infringing the '396 Patent.

642. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to expiration of the '396 Patent will constitute infringement of the '396 Patent under 35 U.S.C. § 271(b).

643. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '396 Patent unless enjoined by the Court.

644. Amicus does not have any adequate remedy at law.

COUNT XXVII

(INFRINGEMENT OF THE '657 PATENT)

645. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

646. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '657 Patent.

647. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '657 Patent are invalid, unenforceable, and/or will not be infringed.

648. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

649. Aurobindo has actual knowledge of the '657 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

650. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '657 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '657 Patent.

651. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '657 Patent.

652. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

653. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '657 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '657 Patent.

654. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

655. Aurobindo has knowledge of the '657 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '657 Patent, either literally or under the doctrine of equivalents.

656. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '657 Patent.

657. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

658. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '657 Patent unless enjoined by the Court.

659. Amicus does not have any adequate remedy at law.

COUNT XXVIII

(INFRINGEMENT OF THE '784 PATENT)

660. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

661. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '784 Patent.

662. Aurobindo's October 2022 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '784 Patent are invalid, unenforceable, and/or will not be infringed.

663. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

664. Aurobindo has actual knowledge of the '784 Patent, as evidenced by Aurobindo's October 2022 Notice Letter.

665. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '784 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786

seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '784 Patent.

666. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '784 Patent.

667. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

668. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '784 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '784 Patent.

669. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

670. Aurobindo has knowledge of the '784 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '784 Patent, either literally or under the doctrine of equivalents.

671. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product

according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '784 Patent.

672. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

673. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '784 Patent unless enjoined by the Court.

674. Amicus does not have any adequate remedy at law.

COUNT XXIX

(INFRINGEMENT OF THE '593 PATENT)

675. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

676. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '593 Patent.

677. Aurobindo's May 2023 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '593 Patent are invalid, unenforceable, and/or will not be infringed.

678. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

679. Aurobindo has actual knowledge of the '593 Patent, as evidenced by Aurobindo's May 2023 Notice Letter.

680. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '593 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '593 Patent.

681. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '593 Patent.

682. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

683. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '593 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '593 Patent.

684. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

685. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '593 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '593 Patent, either literally or under the doctrine of equivalents.

686. Aurobindo has knowledge of the '593 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '593 Patent, either literally or under the doctrine of equivalents.

687. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '593 Patent.

688. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

689. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '593 Patent unless enjoined by the Court.

690. Amicus does not have any adequate remedy at law.

COUNT XXX

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '593 PATENT)

691. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

692. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

693. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the '593 Patent such that the Court may entertain Amicus's request for declaratory relief consistent with Article III of the U.S. Constitution.

694. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '593 Patent.

695. Aurobindo's May 2023 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '593 Patent are invalid, unenforceable, and/or will not be infringed.

696. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

697. Aurobindo has actual knowledge of the '593 Patent, as evidenced by Aurobindo's May 2023 Notice Letter

698. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '593 Patent.

699. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

700. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '593 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '593 Patent.

701. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

702. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '593 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '593 Patent, either literally or under the doctrine of equivalents.

703. Aurobindo has knowledge of the '593 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '593 Patent, either literally or under the doctrine of equivalents.

704. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '593 Patent.

705. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

706. Aurobindo's conduct including, but not limited to, Aurobindo's filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo's ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and meaningful preparations to infringe the '593 Patent and that Aurobindo intends to engage in the commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of

Aurobindo's ANDA Product immediately and imminently upon final approval of Aurobindo's ANDA and prior to the expiration of the '593 Patent.

707. Aurobindo's actions indicate that it does not intend to change its course of action to avoid infringing the '593 Patent.

708. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to expiration of the '593 Patent will constitute infringement of the '593 Patent under 35 U.S.C. § 271(b).

709. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '593 Patent unless enjoined by the Court.

710. Amicus does not have any adequate remedy at law.

COUNT XXXI

(INFRINGEMENT OF THE '594 PATENT)

711. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

712. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '594 Patent.

713. Aurobindo's May 2023 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '594 Patent are invalid, unenforceable, and/or will not be infringed.

714. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of

administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

715. Aurobindo has actual knowledge of the '594 Patent, as evidenced by Aurobindo's May 2023 Notice Letter.

716. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '594 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '594 Patent.

717. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '594 Patent.

718. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

719. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '594 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '594 Patent.

720. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

721. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's

Label, such physicians and patients will make and use the compositions claimed in the '594 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '594 Patent, either literally or under the doctrine of equivalents.

722. Aurobindo has knowledge of the '594 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '594 Patent, either literally or under the doctrine of equivalents.

723. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '594 Patent.

724. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

725. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '594 Patent unless enjoined by the Court.

726. Amicus does not have any adequate remedy at law.

COUNT XXXII

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '594 PATENT)

727. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

728. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

729. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the '594

Patent such that the Court may entertain Amicus's request for declaratory relief consistent with Article III of the U.S. Constitution.

730. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '594 Patent.

731. Aurobindo's May 2023 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '594 Patent are invalid, unenforceable, and/or will not be infringed.

732. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

733. Aurobindo has actual knowledge of the '594 Patent, as evidenced by Aurobindo's May 2023 Notice Letter.

734. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '594 Patent.

735. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

736. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '594 Patent under § 271(b), either literally or under the

doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '594 Patent.

737. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

738. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '594 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '594 Patent, either literally or under the doctrine of equivalents.

739. Aurobindo has knowledge of the '594 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '594 Patent, either literally or under the doctrine of equivalents.

740. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '594 Patent.

741. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

742. Aurobindo's conduct including, but not limited to, Aurobindo's filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo's ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and

meaningful preparations to infringe the ’594 Patent and that Aurobindo intends to engage in the commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of Aurobindo’s ANDA Product immediately and imminently upon final approval of Aurobindo’s ANDA and prior to the expiration of the ’594 Patent.

743. Aurobindo’s actions indicate that it does not intend to change its course of action to avoid infringing the ’594 Patent.

744. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo’s ANDA Product prior to expiration of the ’594 Patent will constitute infringement of the ’594 Patent under 35 U.S.C. § 271(b).

745. Amicus will be substantially and irreparably harmed by Aurobindo’s infringement of the ’594 Patent unless enjoined by the Court.

746. Amicus does not have any adequate remedy at law.

COUNT XXXIII

(INFRINGEMENT OF THE ’962 PATENT)

747. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

748. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo’s ANDA Product before the expiration of the ’962 Patent.

749. Aurobindo’s May 2023 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the ’962 Patent are invalid, unenforceable, and/or will not be infringed.

750. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

751. Aurobindo has actual knowledge of the '962 Patent, as evidenced by Aurobindo's May 2023 Notice Letter.

752. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '962 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '962 Patent.

753. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '962 Patent.

754. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

755. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '962 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '962 Patent.

756. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

757. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '962 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '962 Patent, either literally or under the doctrine of equivalents.

758. Aurobindo has knowledge of the '962 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '962 Patent, either literally or under the doctrine of equivalents.

759. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '962 Patent.

760. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

761. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '962 Patent unless enjoined by the Court.

762. Amicus does not have any adequate remedy at law.

COUNT XXXIV

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '962 PATENT)

763. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

764. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

765. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the '962 Patent such that the Court may entertain Amicus's request for declaratory relief consistent with Article III of the U.S. Constitution.

766. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '962 Patent.

767. Aurobindo's May 2023 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '962 Patent are invalid, unenforceable, and/or will not be infringed.

768. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

769. Aurobindo has actual knowledge of the '962 Patent, as evidenced by Aurobindo's May 2023 Notice Letter.

770. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '962 Patent.

771. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

772. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '962 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '962 Patent.

773. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

774. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '962 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '962 Patent, either literally or under the doctrine of equivalents.

775. Aurobindo has knowledge of the '962 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '962 Patent, either literally or under the doctrine of equivalents.

776. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '962 Patent.

777. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

778. Aurobindo's conduct including, but not limited to, Aurobindo's filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo's ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and meaningful preparations to infringe the '962 Patent and that Aurobindo intends to engage in the commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of Aurobindo's ANDA Product immediately and imminently upon final approval of Aurobindo's ANDA and prior to the expiration of the '962 Patent.

779. Aurobindo's actions indicate that it does not intend to change its course of action to avoid infringing the '962 Patent.

780. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to expiration of the '962 Patent will constitute infringement of the '962 Patent under 35 U.S.C. § 271(b).

781. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '962 Patent unless enjoined by the Court.

782. Amicus does not have any adequate remedy at law.

COUNT XXXV

(INFRINGEMENT OF THE '387 PATENT)

783. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

784. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '387 Patent.

785. Aurobindo's June 2023 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '387 Patent are invalid, unenforceable, and/or will not be infringed.

786. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

787. Aurobindo has actual knowledge of the '387 Patent, as evidenced by Aurobindo's June 2023 Notice Letter.

788. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '387 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '387 Patent.

789. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '387 Patent.

790. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

791. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '387 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '387 Patent.

792. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

793. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '387 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '387 Patent, either literally or under the doctrine of equivalents.

794. Aurobindo has knowledge of the '387 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '387 Patent, either literally or under the doctrine of equivalents.

795. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '387 Patent.

796. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

797. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '387 Patent unless enjoined by the Court.

798. Amicus does not have any adequate remedy at law.

COUNT XXXVI

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '387 PATENT)

799. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

800. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

801. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the '387 Patent such that the Court may entertain Amicus's request for declaratory relief consistent with Article III of the U.S. Constitution.

802. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '387 Patent.

803. Aurobindo's June 2023 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '387 Patent are invalid, unenforceable, and/or will not be infringed.

804. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

805. Aurobindo has actual knowledge of the '387 Patent, as evidenced by Aurobindo's June 2023 Notice Letter.

806. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '387 Patent.

807. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

808. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '387 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '387 Patent.

809. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

810. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '387 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '387 Patent, either literally or under the doctrine of equivalents.

811. Aurobindo has knowledge of the '387 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '387 Patent, either literally or under the doctrine of equivalents.

812. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing

use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '387 Patent.

813. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

814. Aurobindo's conduct including, but not limited to, Aurobindo's filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo's ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and meaningful preparations to infringe the '387 Patent and that Aurobindo intends to engage in the commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of Aurobindo's ANDA Product immediately and imminently upon final approval of Aurobindo's ANDA and prior to the expiration of the '387 Patent.

815. Aurobindo's actions indicate that it does not intend to change its course of action to avoid infringing the '387 Patent.

816. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to expiration of the '387 Patent will constitute infringement of the '387 Patent under 35 U.S.C. § 271(b).

817. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '387 Patent unless enjoined by the Court.

818. Amicus does not have any adequate remedy at law.

COUNT XXXVII

(INFRINGEMENT OF THE '388 PATENT)

819. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

820. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '388 Patent.

821. Aurobindo's June 2023 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '388 Patent are invalid, unenforceable, and/or will not be infringed.

822. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

823. Aurobindo has actual knowledge of the '388 Patent, as evidenced by Aurobindo's June 2023 Notice Letter.

824. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '388 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '388 Patent.

825. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '388 Patent.

826. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

827. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '388 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '388 Patent.

828. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

829. Aurobindo has knowledge of the '388 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '388 Patent, either literally or under the doctrine of equivalents.

830. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '388 Patent.

831. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

832. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '388 Patent unless enjoined by the Court.

833. Amicus does not have any adequate remedy at law.

COUNT XXXVIII

(INFRINGEMENT OF THE '334 PATENT)

834. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

835. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '334 Patent.

836. Aurobindo's June 2023 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '334 Patent are invalid, unenforceable, and/or will not be infringed.

837. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

838. Aurobindo has actual knowledge of the '334 Patent, as evidenced by Aurobindo's June 2023 Notice Letter.

839. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '334 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '334 Patent.

840. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '334 Patent.

841. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

842. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '334 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '334 Patent.

843. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

844. Aurobindo has knowledge of the '334 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '334 Patent, either literally or under the doctrine of equivalents.

845. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '334 Patent.

846. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

847. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '334 Patent unless enjoined by the Court.

848. Amicus does not have any adequate remedy at law.

COUNT XXXIX

(INFRINGEMENT OF THE '516 PATENT)

849. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

850. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '516 Patent.

851. Aurobindo's December 2023 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), a certification alleging that the claims of the '516 Patent are invalid, unenforceable, and/or will not be infringed.

852. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

853. Aurobindo has actual knowledge of the '516 Patent, as evidenced by Aurobindo's December 2023 Notice Letter.

854. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '516 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786

seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '516 Patent.

855. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '516 Patent.

856. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

857. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '516 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '516 Patent.

858. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

859. Aurobindo has knowledge of the '516 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '516 Patent, either literally or under the doctrine of equivalents.

860. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product

according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '516 Patent.

861. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

862. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '516 Patent unless enjoined by the Court.

863. Amicus does not have any adequate remedy at law.

COUNT XL

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '516 PATENT)

864. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

865. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

866. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the '516 Patent such that the Court may entertain Amicus's request for declaratory relief consistent with Article III of the U.S. Constitution.

867. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '516 Patent.

868. Aurobindo's December 2023 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), a certification alleging that the claims of the '516 Patent are invalid, unenforceable, and/or will not be infringed.

869. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

870. Aurobindo has actual knowledge of the '516 Patent, as evidenced by Aurobindo's December 2023 Notice Letter.

871. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '516 Patent.

872. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

873. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '516 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '516 Patent.

874. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

875. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions claimed in the '516 Patent,

and therefore such physicians and patients will directly infringe at least one claim of the '516 Patent, either literally or under the doctrine of equivalents.

876. Aurobindo has knowledge of the '516 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '516 Patent, either literally or under the doctrine of equivalents.

877. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '516 Patent.

878. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

879. Aurobindo's conduct including, but not limited to, Aurobindo's filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo's ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and meaningful preparations to infringe the '516 Patent and that Aurobindo intends to engage in the commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of Aurobindo's ANDA Product immediately and imminently upon final approval of Aurobindo's ANDA and prior to the expiration of the '516 Patent.

880. Aurobindo's actions indicate that it does not intend to change its course of action to avoid infringing the '516 Patent.

881. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to expiration of the '516 Patent will constitute infringement of the '516 Patent under 35 U.S.C. § 271(b).

882. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '516 Patent unless enjoined by the Court.

883. Amicus does not have any adequate remedy at law.

COUNT XLI

(INFRINGEMENT OF THE '255 PATENT)

884. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

885. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '255 Patent.

886. Aurobindo's February 2024 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), a certification alleging that the claims of the '255 Patent are invalid, unenforceable, and/or will not be infringed.

887. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

888. Aurobindo has actual knowledge of the '255 Patent, as evidenced by Aurobindo's February 2024 Notice Letter.

889. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '255 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '255 Patent.

890. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '255 Patent.

891. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

892. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '255 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '255 Patent.

893. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

894. Aurobindo has knowledge of the '255 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '255 Patent, either literally or under the doctrine of equivalents.

895. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '255 Patent.

896. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

897. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '255 Patent unless enjoined by the Court.

898. Amicus does not have any adequate remedy at law.

COUNT XLII

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '255 PATENT)

899. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

900. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

901. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the '255 Patent such that the Court may entertain Amicus's request for declaratory relief consistent with Article III of the U.S. Constitution.

902. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '255 Patent.

903. Aurobindo's May 2024 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '255 Patent are invalid, unenforceable, and/or will not be infringed.

904. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

905. Aurobindo has actual knowledge of the '255 Patent, as evidenced by Aurobindo's May 2024 Notice Letter.

906. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '255 Patent.

907. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

908. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '255 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '255 Patent.

909. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

910. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will use the methods claimed in the ' 255 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '255 Patent, either literally or under the doctrine of equivalents.

911. Aurobindo has knowledge of the '255 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '255 Patent, either literally or under the doctrine of equivalents.

912. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '255 Patent.

913. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

914. Aurobindo's conduct including, but not limited to, Aurobindo's filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo's ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and meaningful preparations to infringe the '255 Patent and that Aurobindo intends to engage in the commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of Aurobindo's ANDA Product immediately and imminently upon final approval of Aurobindo's ANDA and prior to the expiration of the '255 Patent.

915. Aurobindo's actions indicate that it does not intend to change its course of action to avoid infringing the '255 Patent.

916. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to expiration of the '255 Patent will constitute infringement of the '255 Patent under 35 U.S.C. § 271(b).

917. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '255 Patent unless enjoined by the Court.

918. Amicus does not have any adequate remedy at law.

COUNT XLIII

(INFRINGEMENT OF THE '938 PATENT)

919. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

920. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '938 Patent.

921. Aurobindo's May 2024 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), a certification alleging that the claims of the '938 Patent are invalid, unenforceable, and/or will not be infringed.

922. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

923. Aurobindo has actual knowledge of the '938 Patent, as evidenced by Aurobindo's May 2024 Notice Letter.

924. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed at least one claim of the '938 Patent by submitting, or causing to be submitted, to the FDA Aurobindo's ANDA No. 217786 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration date of the '938 Patent.

925. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '938 Patent.

926. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

927. If ANDA No. 217786 is approved, Aurobindo will infringe one or more claims of the '938 Patent under § 271(a), either literally or under the doctrine of equivalents by commercially making, using, offering for sale, selling, and/or importing Aurobindo's ANDA Product within or into the United States and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '938 Patent.

928. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

929. Aurobindo has knowledge of the ’938 Patent and, by virtue of Aurobindo’s Label for Aurobindo’s ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the ’938 Patent, either literally or under the doctrine of equivalents.

930. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo’s Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo’s ANDA Product according to the instructions for use in Aurobindo’s Label in a way that directly infringes at least one claim of the ’938 Patent.

931. Aurobindo’s actions relating to Aurobindo’s ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

932. Amicus will be substantially and irreparably harmed by Aurobindo’s infringement of the ’938 Patent unless enjoined by the Court.

933. Amicus does not have any adequate remedy at law.

COUNT XLIV

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’938 PATENT)

934. Amicus re-alleges and incorporates by reference each preceding paragraph as though fully re-stated herein.

935. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

936. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Amicus and Aurobindo regarding infringement of the ’938 Patent such that the Court may entertain Amicus’s request for declaratory relief consistent with Article III of the U.S. Constitution.

937. Aurobindo filed ANDA No. 217786 indicating its intention and seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '938 Patent.

938. Aurobindo's May 2024 Notice Letter states that Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c), a certification alleging that the claims of the '938 Patent are invalid, unenforceable, and/or will not be infringed.

939. By filing ANDA No. 217786, Aurobindo has represented to the FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GALAFOLD Capsules, and will be pharmaceutically and therapeutically equivalent to GALAFOLD Capsules.

940. Aurobindo has actual knowledge of the '938 Patent, as evidenced by Aurobindo's May 2024 Notice Letter.

941. Subject to receiving final approval of ANDA No. 217786, Aurobindo intends to and will commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product within or into the United States before the expiration of the '938 Patent.

942. Upon information and belief, Aurobindo has represented to the FDA that Aurobindo's ANDA Product will be bioequivalent to GALAFOLD Capsules and will contain 123 mg free base migalastat.

943. If ANDA No. 217786 is approved, Aurobindo will actively induce direct infringement of one or more claims of the '938 Patent under § 271(b), either literally or under the doctrine of equivalents, unless this Court orders that the effective date of any FDA approval of ANDA No. 217786 shall be no earlier than the expiration of the '938 Patent.

944. Aurobindo knows, should know, and intends that physicians will prescribe and patients will take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label.

945. Aurobindo knows, should know, and intends that, when physicians prescribe and patients take Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label, such physicians and patients will make and use the compositions and methods claimed in the '938 Patent, and therefore such physicians and patients will directly infringe at least one claim of the '938 Patent, either literally or under the doctrine of equivalents.

946. Aurobindo has knowledge of the '938 Patent and, by virtue of Aurobindo's Label for Aurobindo's ANDA Product, knows or should know that it will induce direct infringement of at least one claim of the '938 Patent, either literally or under the doctrine of equivalents.

947. Aurobindo is aware, has knowledge of, and/or specifically intends that Aurobindo's Label will encourage, recommend, promote, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's ANDA Product according to the instructions for use in Aurobindo's Label in a way that directly infringes at least one claim of the '938 Patent.

948. Aurobindo's actions relating to Aurobindo's ANDA No. 217786 complained of herein were done by and for the benefit of Aurobindo.

949. Aurobindo's conduct including, but not limited to, Aurobindo's filing of ANDA No. 217786 attempting to meet the regulatory requirements for approval of Aurobindo's ANDA Product, demonstrates that Aurobindo has made and will continue to make substantial and meaningful preparations to infringe the '938 Patent and that Aurobindo intends to engage in the commercial manufacture, use, offer for sale, marketing, distribution, and or/importation of

Aurobindo's ANDA Product immediately and imminently upon final approval of Aurobindo's ANDA and prior to the expiration of the '938 Patent.

950. Aurobindo's actions indicate that it does not intend to change its course of action to avoid infringing the '938 Patent.

951. Amicus is entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to expiration of the '938 Patent will constitute infringement of the '938 Patent under 35 U.S.C. § 271(b).

952. Amicus will be substantially and irreparably harmed by Aurobindo's infringement of the '938 Patent unless enjoined by the Court.

953. Amicus does not have any adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '279 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '279 Patent;

B. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '279 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '279 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

C. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '727 Patent through Aurobindo's submission of ANDA No. 217786 to the

FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '727 Patent;

D. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '727 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '727 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

E. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '889 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '889 Patent;

F. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '889 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '889 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

G. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '890 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '890 Patent;

H. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '890 Patent will infringe,

actively induce infringement, and/or contribute to the infringement of at least one claim of the '890 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

I. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '655 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '655 Patent;

J. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '655 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '655 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

K. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '536 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '536 Patent;

L. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '536 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '536 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

M. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '537 Patent through Aurobindo's submission of ANDA No. 217786 to the

FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '537 Patent;

N. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '537 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '537 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

O. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '538 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '538 Patent;

P. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '538 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '538 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

Q. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '539 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '539 Patent;

R. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '539 Patent will infringe,

actively induce infringement, and/or contribute to the infringement of at least one claim of the '539 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

S. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '540 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '540 Patent;

T. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '540 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '540 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

U. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '761 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '761 Patent;

V. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '761 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '761 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

W. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '762 Patent through Aurobindo's submission of ANDA No. 217786 to the

FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '762 Patent;

X. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '762 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '762 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

Y. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '763 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '763 Patent;

Z. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '763 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '763 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

AA. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '436 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '436 Patent;

BB. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '436 Patent will infringe,

actively induce infringement, and/or contribute to the infringement of at least one claim of the '436 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

CC. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '437 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '437 Patent;

DD. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '437 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '437 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

EE. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '128 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '128 Patent;

FF. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '128 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '128 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

GG. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '940 Patent through Aurobindo's submission of ANDA No. 217786 to the

FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '940 Patent;

HH. The entry of judgment under 35 U.S.C. § 271(b) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '940 Patent will actively induce infringement of at least one claim of the '940 Patent under 35 U.S.C. § 271(b);

II. A judicial declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '940 Patent will actively induce infringement of at least one claim of the '940 Patent under 35 U.S.C. § 271(b);

JJ. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '764 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '764 Patent;

KK. The entry of judgment under 35 U.S.C. § 271(b) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '764 Patent will actively induce infringement of at least one claim of the '764 Patent under 35 U.S.C. § 271(b);

LL. A judicial declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '764 Patent will actively induce infringement of at least one claim of the '764 Patent under 35 U.S.C. § 271(b);

MM. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '765 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '765 Patent;

NN. The entry of judgment under 35 U.S.C. § 271(b) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '765 Patent will actively induce infringement of at least one claim of the '765 Patent under 35 U.S.C. § 271(b);

OO. A judicial declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '765 Patent will actively induce infringement of at least one claim of the '765 Patent under 35 U.S.C. § 271(b);

PP. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '244 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '244 Patent;

QQ. The entry of judgment under 35 U.S.C. § 271(b) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '244 Patent will actively induce infringement of at least one claim of the '244 Patent under 35 U.S.C. § 271(b);

RR. A judicial declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product

before the expiration of the ’244 Patent will actively induce infringement of at least one claim of the ’244 Patent under 35 U.S.C. § 271(b);

SS. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the ’396 Patent through Aurobindo’s submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo’s ANDA Product before the expiration of the ’396 Patent;

TT. The entry of judgment under 35 U.S.C. § 271(b) that Aurobindo’s commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo’s ANDA Product before the expiration of the ’396 Patent will actively induce infringement of at least one claim of the ’396 Patent under 35 U.S.C. § 271(b);

UU. A judicial declaration that Aurobindo’s commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo’s ANDA Product before the expiration of the ’396 Patent will actively induce infringement of at least one claim of the ’396 Patent under 35 U.S.C. § 271(b);

VV. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the ’657 Patent through Aurobindo’s submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo’s ANDA Product before the expiration of the ’657 Patent;

WW. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo’s commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo’s ANDA Product before the expiration of the ’657 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the ’657 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

XX. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '784 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '784 Patent;

YY. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '784 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '784 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

ZZ. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '593 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '593 Patent;

AAA. The entry of judgment under 35 U.S.C. § 271(b) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '593 Patent will actively induce infringement of at least one claim of the '593 Patent under 35 U.S.C. § 271(b);

BBB. A judicial declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '593 Patent will actively induce infringement of at least one claim of the '593 Patent under 35 U.S.C. § 271(b);

CCC. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '594 Patent through Aurobindo's submission of ANDA No. 217786 to the

FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '594 Patent;

DDD. The entry of judgment under 35 U.S.C. § 271(b) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '594 Patent will actively induce infringement of at least one claim of the '594 Patent under 35 U.S.C. § 271(b);

EEE. A judicial declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '594 Patent will actively induce infringement of at least one claim of the '594 Patent under 35 U.S.C. § 271(b);

FFF. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '962 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '962 Patent;

GGG. The entry of judgment under 35 U.S.C. § 271(b) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '962 Patent will actively induce infringement of at least one claim of the '962 Patent under 35 U.S.C. § 271(b);

HHH. A judicial declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '962 Patent will actively induce infringement of at least one claim of the '962 Patent under 35 U.S.C. § 271(b);

III. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '387 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '387 Patent;

JJJ. The entry of judgment under 35 U.S.C. § 271(b) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '387 Patent will actively induce infringement of at least one claim of the '387 Patent under 35 U.S.C. § 271(b);

KKK. A judicial declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '387 Patent will actively induce infringement of at least one claim of the '387 Patent under 35 U.S.C. § 271(b);

LLL. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '388 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '388 Patent;

MMM. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '388 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '388 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

NNN. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '334 Patent through Aurobindo's submission of ANDA No. 217786 to the

FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '334 Patent;

OOO. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '334 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '334 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

PPP. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '516 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '516 Patent;

QQQ. The entry of judgment under 35 U.S.C. § 271(b) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '516 Patent will actively induce infringement of at least one claim of the '516 Patent under 35 U.S.C. § 271(b);

RRR. A judicial declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '516 Patent will actively induce infringement of at least one claim of the '516 Patent under 35 U.S.C. § 271(b);

SSS. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '255 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '255 Patent;

TTT. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '255 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '255 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

UUU. A judicial declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '255 Patent will actively induce infringement of at least one claim of the '255 Patent under 35 U.S.C. § 271(b);

VVV. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the '938 Patent through Aurobindo's submission of ANDA No. 217786 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Aurobindo's ANDA Product before the expiration of the '938 Patent;

WWW. The entry of judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '938 Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '938 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

XXX. A judicial declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product before the expiration of the '938 Patent will actively induce infringement of at least one claim of the '938 Patent under 35 U.S.C. § 271(b);

YYY. The issuance of an order providing that the effective date of any FDA approval of Aurobindo's ANDA Product shall be no earlier than the expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Amicus and/or the Patents-in-Suit become entitled, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

ZZZ. The entry of a permanent and/or preliminary injunction enjoining Aurobindo and all persons acting in concert with Aurobindo from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product, until the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Amicus and/or the Patents-in-Suit are or become entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

AAAA. The entry of a permanent and/or preliminary injunction enjoining Aurobindo and all persons acting in concert with Aurobindo from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the Patents-in-Suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

BBBB. Damages, including under 35 U.S.C. §§ 271(e)(4)(C) and/or 285, or other monetary relief awarded to Amicus if Aurobindo engages in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Aurobindo's ANDA Product prior to the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Amicus is or becomes entitled;

CCCC. A declaration that this is an exceptional case and an award to Amicus of its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

DDDD. An award to Amicus of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

EEEE. An award to Amicus of any further and additional relief that this Court deems just and proper.

Dated: June 13, 2024

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** *pro hac vice* applications forthcoming

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